

WHAT IS CLAIMED IS:

- I
- 1 1. A method for the detection of the onset or presence of sporadic basal cell
  - 2 carcinoma (BCC) in an animal, which comprises measuring the presence and level
  - 3 of expression of Gli1.

- 1 2. The method of Claim 1, wherein the expression of said Gli1 is ectopic
- 2 expression.

- 1 3. The method of Claim 1, wherein said expression is measured by collecting a
- 2 biological sample from said animal suspected of harboring a basal cell carcinoma;
- 3 and culturing said sample with/ treating a of frog embryos for a period of time
- 4 sufficient for the development on said frog embryos of skin tumors;
- 5 wherein the formation/development of said skin tumors is indicative of the
- 6 presence of said basal cell carcinoma.

- II
- 1 4. An assay for the detection of the onset or presence of sporadic basal cell
  - 2 carcinoma (BCC) in an animal, comprising an observable test colony which
  - 3 exhibits the demonstrable development of neoplasia upon contact with ectopically
  - 4 expressed Gli1 from a biological sample taken from an animal; other reagents; and
  - 5 directions for use thereof.

- 1 5. A method of testing the ability of a drug or other entity to modulate the activity
- 2 of Gli1 which comprises:

- III
- 3 A. culturing test cells which demonstrate a tumorous condition and which
  - 4 contain elevated levels of Gli1;
  - 5 B. adding the drug under test; and
  - 6 C. measuring the change if any, in the tumorous condition of said test
  - 7 cells.

- 1 6. An assay system for screening drugs and other agents for ability to modulate

2 the expression of Gli1 in epidermal cells, comprising:

- 3 A. culturing observable test cells inoculated with a drug or agent directed to  
4 Gli1;  
5 B. harvesting a supernatant from said test cells; and  
6 C. examining said supernatant for the presence of a tumorous mass from  
7 sporadic basal cell carcinoma, wherein an increase or a decrease in the size of the  
8 tumorous mass indicates the ability of a drug to modulate the expression or activity  
9 of said Gli1.

1 7. A test kit for the demonstration of basal cell carcinoma in a eukaryotic cellular  
2 sample, comprising:

- 3 A. a predetermined amount of a detectably labelled specific binding partner  
4 to Gli1;  
5 B. other reagents; and  
6 C. directions for use of said kit.

1 8. A method of preventing and/or treating cellular debilitations, derangements  
2 and/or dysfunctions and/or other disease states in mammals caused by the  
3 development and presence of sporadic basal cell carcinoma, comprising  
4 administering to a mammal a therapeutically effective amount of a material selected  
5 from the group consisting of inhibitors of the expression and activity of Gli1, their  
6 complements or fragments thereof, and mixtures thereof, or a specific binding  
7 partner thereto.

1 9. A pharmaceutical composition for the treatment of cellular debilitations,  
2 derangements and/or dysfunctions and/or other disease states in mammals caused by  
3 the development and presence of sporadic basal cell carcinoma, comprising a  
4 therapeutically effective amount of a material selected from the group consisting of  
5 inhibitors of the expression and activity of Gli1, their complements or fragments  
6 thereof, and mixtures thereof, or a specific binding partner thereto; and a  
7 pharmaceutically acceptable carrier therefor.